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09/912,157	07/24/2001	Scott R. Presnell	00-49	3977

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ZymoGenetics, Inc.  
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[REDACTED] EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
1647	[REDACTED]

DATE MAILED: 02/10/2003

X

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

## Office Action Summary

Application No. <b>09/912,157</b>	Applicant(s) <b>Presnell et al.</b>
Examiner <b>Fozia Hamud</b>	Art Unit <b>1647</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on May 28, 2002.

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-17 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims 1-17 are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some\* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)      4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      6)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3, 15-17 drawn to an isolated polypeptide comprising a specific amino acid sequence, classified in class 530, subclass 350.
  - II. Claims 4-12, drawn to an isolated nucleic acid molecule, a vector comprising said nucleic acid, a host cell comprising said nucleic acid molecule and a method of producing a polypeptide by culturing said host cell, classified in class 435, subclass 69.1.
  - III. Claims 13-14, drawn to an antibody which selectively binds to a polypeptide, classified in class 530, subclass 389.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acid of Group II can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of Group I can be used other than to make the antibody of Group III, such as used as a probe, or used therapeutically or diagnostically (e.g. in screening). Although the antibody of Group III can be used to obtain the nucleic acid of Group II, it can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or it may be used therapeutically.

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Since the invention of Group II includes a method of using the polynucleotide to make the polypeptide of group I, inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Group I can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

[A] an isolated polypeptide comprising amino acid sequence selected from the group consisting of: (a) amino acid residues 36 to 189 of SEQ ID NO:2, (b) amino acid residues 1 to 189 of SEQ ID NO:2, (c) amino acid residues 36 to 313 of SEQ ID NO:2, (d) amino acid residues 336 to 753 of SEQ ID NO:2, (e) amino acid residues 36 to 753 of SEQ ID NO:2, (f) amino acid residues 1 to 753 of SEQ ID NO:2, (g) amino acid residues 1 to 299 of SEQ ID NO:8, (h) amino acid residues 36 to 299 of SEQ ID NO:8, (I) amino acid residues 36 to 175 of SEQ ID NO:8, (j) amino acid residues 1 to 300 of SEQ ID NO:12, (k) amino acid residues 36 to 300 of SEQ ID NO:12.

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[B] And an isolated nucleic acid encoding a polypeptide comprising an amino acid sequence selected from the group consisting of: (a) amino acid residues 36 to 189 of SEQ ID NO:2. (b) amino acid residues 1 to 189 of SEQ ID NO:2, [c] amino acid residues 36 to 313 of SEQ ID NO:2, (d) amino acid residues 336 to 753 of SEQ ID NO:2 (e) amino acid residues 36 to 753 of SEQ ID NO:2, (f) amino acid residues 1 to 753 of SEQ ID NO:2, (g) amino acid residues 1 to 299 of SEQ ID NO:8, (h) amino acid residues 36 to 299 of SEQ ID NO:8, (I) amino acid residues 36 to 175 of SEQ ID NO:8, (j) amino acid residues 1 to 300 of SEQ ID NO:12, (k) amino acid residues 36 to 300 of SEQ ID NO:12.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. If Applicants elect either invention of Groups I or II, they must also elect one of the species above. Currently, claims 1, 4 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursdays from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
03 February 2003

  
YVONNE EYLER, PH.D  
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